



Military Medical Research News

Vol. 4, Issue 9 ▪ September 2017

Building hope, saving lives through research Team fine-tunes therapy, training to avert suicide in uniform

by Paula Amann

In a small booth with a glass window, Navy Lt. Jamil Khan sat listening intently to the young man seated across from him. Khan, a Protestant chaplain, reached for the right words to respond.

The topic was suicide and though the man was an actor, not a real service member, his story was like many actual ones. In real life, the need for an effective response can be urgent. According to a 2014 report from the Armed Forces Health Surveillance Center, suicide accounts for 28 percent of all deaths in the U.S. military – more than any other underlying cause.

The encounter just described took place Aug. 7-11 at the Val G. Hemming Simulation Center at the Uniformed Services University of the Health Sciences (USU). The Suicide CPR (Care, Prevention and Research) Initiative led the training for the Chaplains–Care Program.

Marjan Ghahramanlou-Holloway, Ph.D., an associate professor of medical and clinical psychology at USU, directs this initiative. Patients from Walter Reed National Military Medical Center have stepped up to enable the research behind the program.

“This is not just a military issue but an issue for the medical community,” Ghahramanlou-Holloway said. “We have not had a lot of evidence-based, psycho-therapeutic practices to treat suicidality.”

For their part, military chaplains have a unique opportunity to redirect the life path of service members at risk for suicide, she said.

“Chaplains provide 100 percent confidentiality,” unlike mental health care providers, Ghahramanlou-Holloway

said. Service members concerned about their reputation and careers, she explained, might be more willing to open up to a chaplain.

Over five days, the director and her staff trained Khan and 10 other Navy chaplains on cognitive behavioral strategies to prevent suicide. Rooted in cognitive behavioral theory,

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Lt. Cmdr. Pat Coley, a chaplain, left front, and Karina Vesco, a licensed clinical social worker, listen to a Navy chaplain and an actor playing a service member at risk for suicide, Aug. 4, 2017. Coley and Vesco were mentors in the Chaplains–Care Program in Military Suicide Prevention, created by the Suicide CPR Initiative of the Uniformed Services University of the Health Sciences. Patients at Walter Reed Bethesda took part in the research behind this training (Photo by Jessica LaCroix)



DEPARTMENT OF RESEARCH PROGRAMS



Army Col. Peter Weina, chief of Department of Research Programs (official photo)

The Department of Research Programs at Walter Reed National Military Medical Center supports research in the National Capital Region.

This monthly newsletter covers events, research and administrative policies and procedures, research studies and collaborations, department operations, workshops and other programs across our region.

MILITARY MEDICAL RESEARCH NEWS

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This newsletter appears monthly. We welcome your story ideas, comments, corrections and photographs (action shots are best). *Please send any timely information by the 15th day of the prior month for the following month's issue.* Send your ideas, pictures or infographics to paula.m.amann.ctr@mail.mil.

Not on our email list? Don't miss an issue! Please drop us an email, and we will add you to our distribution list.

RESEARCH FIRST STEPS

Our research protocol specialists (formerly protocol navigators) are available to help you start the process and assist you with your submission. To make an appointment with a protocol specialist, please call the Department of Research Programs (DRP) office at 301-295-8239. DRP is located in Building 17B, on the third floor, to the left of the elevators.

RESEARCH ROUNDTABLE SCHEDULE

Walter Reed National Military Medical Center

America Building (Building 19), Second floor, Room 2301

- ♦ Tuesday, September 19, 1200-1300
"Introduction to the Henry Jackson Foundation"
- ♦ Tuesday, October 17, 1200-1300

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EIRB TIP OF THE MONTH Evergreen Advice

Name it right.

Our system has a convention for submission component naming in documents. Please note: The version information will automatically populate in the Submission Components area when you enter the document's version information in EIRB.

Check that the version information you enter in EIRB matches what appears on any document you upload into the system. Please use intuitive titles, labels and names for documents such as consent forms that you upload into EIRB. For instance, if you have more than one consent form, say so.

Parse your populations.

Please review section instructions for a template or form, as the instructions describe the information the reviewers are seeking. For example, the EIRB protocol application has separate sections for target population and subject population. Each calls for different information.

**—Tips courtesy of Wendy Gilbert,
Institutional Review Board manager**



ANNOUNCEMENTS

Department launches new series

Want to add new skills in research to your midday meal? Join us for Lunch and Learn: Research 2.0, a twice-monthly series from the Department of Research Programs.

Each session will focus on a given skill, from designing a pilot study and estimating sample size to gaining electronic consent and speeding up your protocol approval. What's more, you can earn credits for Minimum Education Requirements Framework (MERF) by taking part in any trainings on human subjects protection.

The series will toggle between live presentations by veteran staff from the department and webinars from the PRIM&R series on a host of topics related to research.

Please put Lunch and Learn: Research 2.0 on your calendar for the second and fourth Wednesdays. This month, the Lunch and Learn features webinars on data and safety monitoring on Sept. 13, followed by the ethics and regulations linked to clinical trials on Sept. 27. Bring your own lunch and a desire to build new skills.

The Oct. 11 Lunch and Learn will feature the webinar, "Early Feasibility Studies for Investigational Devices." On Oct. 25, our research attorney, Martin Hindel, will demystify the collaborative research and development agreement (CRADA) with "Introduction to Technology Transfer."

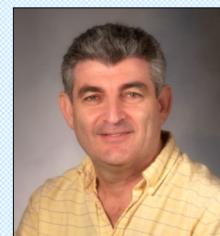
Dashboard can help track research portfolios

Wondering what's going on with research in your corner of the hospital? The Dashboard Database has answers. Army Col. Peter J. Weina, chief of the Department of Research Programs, urges all section chiefs to check the database regularly. From Immunology and Cardiology to Orthopedics and Rheumatology, the dashboard can track research projects by specialty. To get connected, contact Dan Brooks at daniel.i.brooks3.ctr@mail.mil.

Speaker looks to future of research

Shai D. Silberberg will speak on the topic, "Assuring a Bright Future for Biomedical Research." The lecture and discussion is set for 2 to 3:30 p.m. on Sept. 25 in the Great Lakes Rooms 2525 A, B and C of Building 19. Silberberg is director of research quality at the National Institute of Neurological Disorders and Stroke.

The Department of Research Programs cohosts the event with the Health Services Research Program at Uniformed Services University, as part of a series of guest speakers on medical research. □



Shai Silberberg
(Photo courtesy
of subject)

GETTING STARTED WITH THE INSTITUTIONAL REVIEW BOARD AT WALTER REED BETHESDA

A convened IRB panel meets twice a month, with actions assigned based on submission deadlines.

Submission deadlines are the dates that the IRB receives a submission with all administrative, scientific and any other required pre-reviews *already done*. Please work with a research protocol specialist and refine your project in time to make these deadlines.

Expedited actions have no submission deadlines, because the IRB reviews them independently of the convened meeting schedule.

However, please follow these deadlines to help build our IRB agenda for the rest of 2017. Thank you for your cooperation.

Convened IRB Meetings	Submission Deadlines (Time: 1600)
September 28	September 14
October 12	September 28
October 26	October 12
November 9	October 26
November 16	November 2
December 14	November 24
December 21	December 7



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these strategies seek to change the patterns of thinking or behavior behind personal problems.

For his part, Khan, who serves at Camp Lejeune in Jacksonville, North Carolina, had high praise for the Chaplains–Care training.

“I loved it,” said Khan. “It wasn’t a typical [slide show] being thrown at you.”

The chaplain cited the practical tools he learned, such as asking clients open-ended questions, talking with them about reasons for living and creating a “hope box.”

“I put the techniques to use as soon as I came back,” Khan said. Days after the program, the chaplain reported counseling three Marines who were considering suicide and another who had lost his mother to suicide.

In June, Jessica LaCroix, Ph.D., a research psychologist and co-principal investigator, presented the results of two recent pilot trials of suicide prevention psychotherapy at “Aeschi 9: Suicide Across the Lifespan: Relational Modes of Treatment,” a conference on June 8-10 of this year.

The two trials of cognitive behavioral therapy (CBT) with service members hospitalized for suicide attempts at Walter Reed Bethesda and Ft. Belvoir Community Hospital have shown promise, said LaCroix.

One trial reduced hopelessness, alcohol use and post-traumatic stress disorder. In a second trial, suicide ideation and depression decreased.

Researchers relied on five measures to gauge the impact of the intervention. The measures consisted of the Beck Depression Inventory, the Beck Hopelessness Scale, the Beck Scale for Suicide Ideation, alcohol use and symptoms of post-traumatic stress disorder.

The key to both trials was Post Admission Cognitive Therapy (PACT), a form of CBT that Ghahramanlou-Holloway adapted to the psychiatric inpatient setting



At rear, Lt. Jamil Khan, a chaplain, listens to an actor portraying a suicidal service member in a role-play at the Chaplains-Care Program in Military Suicide Prevention, Aug. 4, 2017. (Photo by Jessica LaCroix)

in 2006. PACT builds on an intervention conceived by Aaron Beck, a psychiatrist and pioneer in suicide prevention.

PACT involves six 60 to 90-minute, one-on-one sessions delivered over the three to four days that survivors of suicide attempts typically spend in the hospital.

“Before PACT, there wasn’t a suicide intervention protocol for the inpatient setting,” LaCroix said. In the past, she explained, mental health care providers looked to “trickle down” treatment for suicide risk through

therapy for psychiatric conditions such as depression and borderline personality disorder.

Prior studies have pinpointed eight hours of this therapy as the effective “dosage,” Ghahramanlou-Holloway noted. In Phase I of PACT, therapists begin by listening to the patient’s story.

Tools for Suicide Prevention

- ⇒ Engage the patient.
- ⇒ Tell the suicide story.
- ⇒ Devise a safety plan.
- ⇒ Build hope (e.g., create a “hope box,” with symbols of reasons for living).
- ⇒ Teach coping strategies (e.g., regulating emotions and solving problems).
- ⇒ Grow a support network.
- ⇒ Review the suicide story and safety plan.
- ⇒ Encourage aftercare.

– Adapted from phases of Post Admission Cognitive Therapy (PACT), developed by Marjan Ghahramanlou-Holloway and based on an intervention conceived by Aaron Beck

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Lt. Robert Hess, a chaplain, counsels an actress who plays a service member during training for the Chaplains-Care Program in Military Suicide Prevention, Aug. 4, 2017. The chaplain trainees practice cognitive behavioral strategies to support service members at risk of suicide. (Photo by Jessica LaCroix)

In 2005, however, a study by Gregory Brown et al. in the *Journal of the American Medical Association* looked at the impact of 10 sessions of CBT on 120 adults who had attempted suicide. That limited sequence of therapy showed dramatic results.

“They literally cut the number of suicide attempts in half,” said LaCroix.

In 2012, an article by M. David Rudd in *Military Psychology* moved prevention research one step further, reviewing effective treatments for what he termed suicidality.

Rudd touted use of brief CBT (BCBT) in the military, where mission demands may preclude use of long-term psychotherapy.

“The targeted and time-limited nature of BCBT offers unique potential for military populations given the constraints and demands of psychotherapy during high operational tempo in wartime,” Rudd wrote.

In the coming months, the Suicide CPR team will be testing the PACT model on a sample large enough to yield strong evidence for its efficacy in stemming the suicide among service members.

Next on the research docket for Ghahramanlou-Holloway and LaCroix is a multisite, randomized, controlled study of PACT. As of late August, the team needed just 30 more participants to step forward and bring the desired total to 218.

“The reason we’re doing this study is to find a definitive answer” to the most effective treatment for service members hospitalized after suicide attempts, Ghahramanlou-Holloway said.

Meanwhile, she and her colleagues are turning their current findings into training not only for chaplains but also for rank-and-file service members. They are designing a new curriculum for recruits in basic training, also funded by the Defense Suicide Prevention Office.

Over three to four group meetings, recruits will learn suicide prevention skills such as emotional regulation and problem solving.

The overarching goal is that “when they have a suicidal crisis or a life crisis, they have some skills for managing the situation effectively and not having it become a catastrophic situation for them and their families,” Ghahramanlou-Holloway said.

As she surveyed the work ahead, Ghahramanlou-Holloway also paid tribute to the service members who take part in her team’s suicide prevention studies. In effect, these research participants are harnessing their personal pain to help drive progress in mental health care, she suggested.

“We couldn’t figure out this puzzle of suicide prevention ... without their input, without their help, without their guidance,” Ghahramanlou-Holloway said. “Their stories help us tailor these interventions.” □



Honoring our own during colors ceremony

Hospital, directorate leaders salute Navy-wide research winners

by Lisa P. Thompson

Winners of the Navy-wide Academic Research Competition (ARC) from Walter Reed National Military Medical Center got a moment in the sun at morning colors on Aug. 8.

The hospital's director, Navy Capt. Mark Kobelja, joined Navy Cmdr. Robert Liotta, director of the Directorate of Education, Training and Research in honoring local winners of the May 25 event in Portsmouth, Virginia.

The research competition rotates annually among Naval Medical Center Portsmouth, Naval Medical Center San Diego and Walter Reed Bethesda.

"One purpose of the ARC is to reward and recognize those that have spent their time engaging in research during the past year," Liotta said. "Another purpose is to select the best medical research among the three MTFs [medical treatment facilities]."

Four researchers from Walter Reed Bethesda came home with awards, as noted in prior issues of this newsletter. Two of the quartet attended the Aug. 8 ceremony: Army Capt. Brenton Franklin and Navy Lt. Luke Johnston.

Franklin won the first-place award in clinical research by staff and fellows, and Johnston finished in second place for clinical research by trainees. Army Capt. Christopher

Daniels won the top basic science award for trainees, and Army Maj. Kristen Zeligs earned second place in basic science for staff.

The judges also bestowed special awards for readiness, health and partnerships. These awards stem from strategic goals set by Vice Admiral C. Forrest Faison III, the Navy Surgeon General and chief of the Bureau of Medicine and Surgery, noted Liotta at the colors ceremony.

Two members of the Walter Reed Bethesda team earned such honors.

"Zeligs won the partnerships award for strengthening our partnerships through incorporation of research, principles and practices of its operational colleagues," explained Liotta. "Johnston received the health award for keeping Navy medicine's main focus on providing patients with the best possible care."

Liotta also thanked Lisa Thompson for her help coordinating this year's competition with its Portsmouth organizers. Next spring, Walter Reed Bethesda will host the event. □

Lisa Thompson serves as supervisory medical education specialist in the Department of Research Programs.



Navy Capt. Mark Kobelja, director of Walter Reed National Military Medical Center, far right, joins Navy Cmdr. Robert Liotta, director of the Education, Training, and Research Directorate, far left, and the author, second from left, Navy Lt. Luke Johnston, center, and Army Capt. Brenton Franklin at the colors ceremony on Aug. 8 (Photo by Strategic Communications).



RESEARCH ROUNDTABLE

A MESSAGE FROM THE HOST OF THE RESEARCH ROUNDTABLE

by Lisa Thompson



Lisa Thompson,
academic research
education specialist
(Photo by subject)

The Department of Research Programs (DRP) would like to offer a 10-15 minute presentation to your staff. Our talk ranges from DRP services to upcoming events and policy updates from the Office of the Under Secretary of Defense [Personnel & Readiness and Research Regulatory Oversight Office (R202)], a review of the Minimum Education Requirements Framework (MERF), and information on required Collaborative Institutional Training Initiative (CITI) training. We would like to join you annually or every six months, before or after your program meets for didactic or lecture hall sessions.

Our goal is to promote research. We want to help familiarize your Graduate Medical Education (GME) trainees, faculty, and staff with DRP services to help them meet their research and scholarly project program requirements. Our services include assistance with protocol development, courses on research methods, statistics, and grant writing, GME trainee research project funding opportunities, collaborative agreements development, manuscript editing, publication clearance, and bench research space through our Biomedical Research Laboratory.

DRP invites you to join us at the Research Roundtable on the third Tuesday of most months. Please rejoin us for the next roundtable on Sept. 19, as **Sheara Fewell**, technical advisor for client relations for the National Capital Region at the **Henry M. Jackson Foundation**, gives an introduction to the foundation's services.

We invite you to present as well. If there is a pressing concern you would like addressed or if you would like to lead a discussion on a research-related topic, please talk to me at the Research Roundtable or send an email to lisa.p.thompson5.civ@mail.mil.

Interested in data analysis?

**Let the biostatistics team at the Department of Research Programs help.
With two weeks' notice, we can lecture on many topics for you and five or more people:**

- *Introduction to statistics (including types of variables, hypothesis testing)*
- *Sample size estimation*
- *Multiple comparisons between groups*
- *Confidence intervals*
- *Randomized clinical trials – the Consolidated Standards of Reporting Trials (CONSORT) checklist*
- *Clinical research design (including retrospective, prospective and case control)*
- *Diagnostic tests for sensitivity and specificity*
- *Estimating reliability between raters*
- *Odds ratios and relative risks*
- *Regression analysis*
- *Principal component analysis and factor analysis*
- *Introduction to Statistical Package for Social Sciences (SPSS)*
- *Analyzing with Excel (including pivot tables, row and column calculations, and graphing)*
- *New this year: Introduction to R (a statistical programming language)*

Got questions? Suggestions? Ready to schedule a class?

Contact Francois Tuamokumo, Ph.D., at francois.tuamokumo.civ@mail.mil



Bringing 'plain language' to research writing

Hands-on workshop helps launch Lunch and Learn: Research 2.0

by John Fadoju

Around the Desert Conference Room on Aug. 22, nurses, doctors and research coordinators gathered to tackle a job outside their usual duties. The group split and trimmed sentences, turned passive verbs into active voice and reworded sentences for power.

This skill building focus exemplifies the style for the new "Lunch and Learn: Research 2.0" series, which will be held twice every month in room 1369, Building 8 (Chapel hallway).

Attendees may earn hourly credits for the Minimum Educational Requirements Framework (MERF) by attending sessions on human research protection policies.

As the first presenter for this new series, Paula Amann, a research technical writer for the Department of Research Programs, shared writing tips in a presentation entitled "Strong Words: Power Tools for Research Writing."

Amann talked about the "plain language" approach, and the need to write clearly in order to communicate with people effectively. She explained the importance of word count, gauging one's reading level and how to configure Microsoft Word to show "readability statistics" after each spelling check.

Make sure you split long sentences, cut extra words, use active verbs and pick the strongest words, Amann stressed.



Paula Amann, research technical writer and editor of the department's monthly newsletter (Photo by John Fadoju)

To put these ideas into practice, she gave the audience lengthy sentences to edit. After each exercise, participants shared their solutions for the writing problems spotlighted.

Amann also shared tips on word choice. She encouraged the audience to use words that have some sensory element to them.

"Words like stem instead of originate, launch instead of establish speak to people," Amann said.

She also shared a few of the concise terms preferred over lengthy ones in the Writing Style Guide and Preferred Usage for DoD Issuances. Instead of "in the near future," for example, the guide suggests "soon."

The audience edited a paragraph from a research consent form, using what they had learned. This program was the first of many for the Lunch and Learn: Research 2.0 series. The Department of Research Programs has scheduled presentations by veteran staff for the next six months.

Also in the series are webinars from Public Responsibility in Medicine and Research (PRIM&R) on topics ranging from data and safety monitoring and electronic informed consent to best practices for assessing risk in social and behavioral research. All are welcome to attend. □

Writing Rx

Free Editorial Services

Department of Research Programs

- * **Set up a private writing consultation.**
- * **Get a professional edit of your manuscript.**
- * **Request a writing workshop for your team.**



Reach out to a friendly editor.
[Email paula.m.amann.ctr@mail.mil](mailto:paula.m.amann.ctr@mail.mil)



DARNALL MEDICAL LIBRARY

Research and Scholarly Communication Support

Sarah Cantrell, Michele Mason-Coles, and Lyubov Tmanova, our librarians, offer research support to Walter Reed Bethesda's medical community. They lead research-oriented classes on a quarterly basis. Individual and group consultations are available upon request.

Research and Scholarly Communication Classes ▪ Building 5, Room 4011

Managing Reference Citations

Tuesday, Sept. 12, 12 p.m. ▪ Building 1, Room 209

Instructor: Dr. Lyubov Tmanova

This lecture will help you to develop basic skills in bibliographic management using EndNote standalone citation manager. Attendees will learn how to create a reference library, collect reference citations from various biomedical literature databases, organize references, generate and format bibliographies, share a library with peers, and connect with researchers.

PubMed

Thursday, Sept. 21, 1 p.m. ▪ Building 6, Room 1369

Instructor: Michele Mason-Coles

Discover the secrets of effectively searching PubMed (MEDLINE), the world's leading biomedical literature database! In this workshop, you will learn best practices of keyword searching, how PubMed interprets your searches, the role of Medical Subject Headings (MeSH), and how to craft an advanced search. Additionally, we will explore how to filter and refine search results, locate related citations, and find the full-text article.

Medical Genetics Resources I

Wednesday, Sept. 27, 12 p.m. ▪ Building 1, Room 209

Instructor: Dr. Lyubov Tmanova

This lecture introduces molecular databases centered on medical genetics, genetic tests, and laboratories, all from the the National Center for Biotechnology Information.

Keeping Up with the Literature

Thursday, Oct. 5, 1 p.m. ▪ Building 1, Room 209

Instructor: Sarah Cantrell

Keeping up with current biomedical research can be overwhelming. Imagine having one single list of articles from your favorite journals, newspapers, web sites, and blogs which you could peruse at your leisure. We will show you ways you can keep current by setting up search alerts and browsing your top journals in a mobile-friendly way. In just 45 minutes, you will learn all you need to know to get started!

TRAINING FOR RESEARCHERS

Ready for research? The Department of Research Programs has the right training for your role. We offer workshops for researchers working with human subjects:

- Collaborative Institutional Training Initiative (CITI)
- Minimum Educational Requirement Framework (MERF)

Arrange training for your department or join our monthly classes. We have only eight spaces per class, so sign up today!

Your Monthly Class

Find it in Heroes Building (Building 5), fourth floor:

- Sept. 13, 3 p.m., Computer Classroom 4 (Room 4031)
- Oct. 10, 2 p.m., Computer Classroom 1 (Room 4010)
- Nov. 14, 3 p.m., Computer Classroom 2 (Room 4011)

Questions? Please contact Ms. Lisa Thompson, supervisory research education specialist, at 301-295-8231 or lisa.p.thompson5.civ@mail.mil.



You belong in the CITI. Start training today!



FACES OF RESEARCH

Solar eclipse piques fascination of a science-minded staff

For many among the staff of the Department of Research, grappling with science is part of the job. On Aug. 21, as a solar eclipse was on view in the area, many took a few moments to switch their sights from medicine to astronomy.



One stage of the solar eclipse over Walter Reed Bethesda, Aug. 21, 2017. (Photo by Martin Hindel)

Staff members took quick breaks on the terrace of Building 17B to watch the rare display. They shared dark glasses, home-made viewers and a batch of “eclipse cookies” baked for the occasion by Robin Howard, the



Martin Hindel, research attorney, throws a shadow of the solar eclipse with a homemade “camera obscura,” as Beth Narvaez, IRB manager, center, and Angela Drago, research support specialist for the IRB, snap pictures. (Photo by Robin Howard)



The chief of the Department of Research Programs, Army Peter J. Weina, takes in the eclipse on the terrace of Building 17B. (Photo by Robin Howard)

the department’s civilian deputy chief. Research attorney Martin Hindel helped colleagues view shadows of the hidden sun with the help of a homemade “camera obscura.”

Even Army Col. Peter J. Weina, chief of the department, took a few moments out to gaze skyward, using a special set of eclipse-viewing glasses. □



Robin Howard, civilian deputy chief of the department, created this set of “eclipse cookies,” showing the solar phenomenon in different phases. (Photo by Martin Hindel)



RESEARCH POLICY RESOURCES

The appearance of external hyperlinks does not constitute endorsement by the U.S. Department of Defense of the linked websites, or the information, products or services contained therein. For other than authorized activities such as military exchanges and Morale, Welfare and Recreation (MWR) sites, the Defense Department does not exercise any editorial control over the information you may find at these locations.

- [Belmont Report](#)
The Belmont Report provides "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" that is found in Code of Federal Regulations, 45 CFR part 46.
- [Comparison of FDA and HHS Regulations](#)
The FDA provides a chart comparing FDA's regulations for human subject protection with those of the Department of Health and Human Services.
- [The President's Council on Bioethics](#)
This web site provides useful references on ethical issues that arise from advances in biotechnology and biomedical sciences.
- [Clinical Trials.gov](#)
Clinical Trials is a service of the National Institutes of Health, provides free public access to a database of Federal and private studies taking place nationwide and provides information on clinical studies for a wide range of diseases and conditions.
- [HHS Office for Human Research Protections](#)
HHS OHRP provides assurances and IRB registration, education, policy guidance, and workshops.
- [HHS Office of Civil Rights](#)
HHS Office of Civil Rights provides guidance on the Health Insurance Portability and Accountability Act (HIPAA) and Standards for Privacy of Individually Identifiable Health Information (the Privacy Rule).
- [MedlinePlus](#)
MedlinePlus provides medical research literature including full-text drug information and an illustrated medical encyclopedia.
- [Office for Human Research Protections \(OHRP\)](#)
OHRP Guidebook (1993) provides current and historical materials about human subject protection. Caution: this serve as a guide and some information is obsolete; however, some portions remain valid.
- [Federal Policy for the Protection of Human Subjects \('Common Rule'\)](#)
HHS provides information about HHS regulations, 45 CFR part 46 and four subparts a, b, c, and d.
- [Protocol Review](#)
HHS provides guidance for protocol development, use of IRB, and Expedited Review procedures and exemptions.
- [Informed Consent](#)
*HHS provides informed consent requirements, guidance on the use of exculpatory language, legal obligation and penalties, documentation and changes to **documentation**.*
- [Vulnerable Populations](#)
HHS provides guidance for populations including prisoners, children, and HIV human subjects.

FDA Regulations

- [CFR – Code of Federal Regulations Title 21](#)
- [FDA Regulations Relating to Good Clinical Practice and Clinical Trials](#)
- [Preambles to GCP Regulations](#)
- [Electronic Records; Electronic Signatures \(21 CFR Part 11\)](#)
- [Regulatory Hearing Before the Food and Drug Administration \(21 CFR Part 16\)](#)
- [Protection of Human Subjects \(Informed Consent\) \(21 CFR Part 50\)](#)
- [Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products \(21 CFR Parts 50 and 56\)](#)
- [Informed Consent Elements \(21 CFR 50.25\(c\)\)](#)
- [Exception From General Requirements for Informed Consent \(21 CFR 50.23\(e\)\)](#)
- [Financial Disclosure by Clinical Investigators \(21 CFR Part 54\)⁸](#)
- [Institutional Review Boards \(21 CFR Part 56\)⁹](#) □

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- FDA IRB Registration Rule (21 CFR 56.106)
- FDA IRB Registration Rule (21 CFR 56.106) (printable PDF version)
- Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58)
- Investigational New Drug Application (21 CFR Part 312)
- Foreign Clinical Trials not conducted under an IND (21 CFR 312.120)
- Expanded Access to Investigational Drugs for Treatment Use (PDF - 216KB)
- Charging for Investigational Drugs (PDF - 204KB)
- Form 1571 (Investigational New Drug Application)
- Form 1572 (Statement of Investigator)
- Applications for FDA Approval to Market a New Drug (21 CFR Part 314)
- Bioavailability and Bioequivalence Requirements (21 CFR Part 320)
- Applications for FDA Approval of a Biologic License (21 CFR Part 601)
- Investigational Device Exemptions (21 CFR Part 812)
- Premarket Approval of Medical Devices (21 CFR Part 814)
- Exception From General Requirements for Informed Consent (21 CFR 50.23(e))

Reporting Problems to the FDA

- [Reporting Complaints Related to FDA-Regulated Clinical Trials](#)
- [Mandatory IRB Reporting: FDA Contacts](#)
- [Clinical Trial Forms](#)

The Department of Research Programs presents

TRAINING FOR ELECTRONIC INSTITUTIONAL REVIEW BOARD (EIRB)

QUESTION AND ANSWER SESSIONS

Time slot: First & Third Mondays 1200–1300

Month	Dates <i>Radiology Conference Room B015, Building 19, Basement</i>
September	18
October	2 16
November	6 20



RECENT PUBLICATIONS

Courtesy of Darnall Medical Library

Find articles by authors at Walter Reed Bethesda in bold.

- Colborn VA, LaCroix JM, Neely LL, et al. [Motor impulsivity differentiates between psychiatric inpatients with multiple versus single lifetime suicide attempts](#). *Psychiatry Res*. 2017;253:18-21. Walter Reed Bethesda author: **Grammer G**
- Darter BJ, Bastian AJ, **Wolf EJ**, **Husson EM**, Labrecque BA, **Hendershot BD**. [Locomotor adaptability in persons with unilateral transtibial amputation](#). *PLoS One*. 2017;12(7):e0181120.
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